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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,620	02/04/2004	Jonathan M. Graff	UN1919/4-8US	9412

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EXAMINER

REDDIG, PETER J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/771,620	Applicant(s) GRAFF ET AL.	
	Examiner Peter J. Reddig	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/31/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The response filed on May 31, 2006 to the restriction requirement of December 2, 2005 has been received. Applicant has elected Group 2, claims 1-3, 6-8, 18-20, 22-24, 34-36, and 38-40 in part as they apply to protein based methods, and claims 14-17, 21, 31-33 and 37 in their entirety, and breast cancer as the disease for examination and FLJ20174 as the genetic marker for examination. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse MPEP 818.03(a).

Upon review and reconsideration, the previous restriction requirement is hereby vacated.

The new restriction requirement follows.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-8, and 14 in part as they apply to nucleic acid based methods, and claims 4, 5, and 9-13, in their entirety, drawn to nucleic acid based methods for diagnosing breast cancer in a subject, classified in class 435, subclass 6.

(Upon election of Group I, applicant must further choose ONE nucleic acid molecule SEQ ID NO: from Claim 9, as each nucleic acid molecule represents an independent invention, not a species)

- II. Claims 18-20 and 22-24 in part as they apply to nucleic acid based methods, and claims and 25-30 in their entirety, drawn to nucleic acid based methods for

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assessing prognosis of a breast or ovarian cancer subject, classified in class 435, subclass 6.

(Upon election of Group II, applicant must further choose ONE nucleic acid molecule SEQ ID NO: from Claim 25, as each nucleic acid molecule represents an independent invention, not a species)

- III. Claims 34-36 and 38-40 in part as they apply to nucleic acid based methods, drawn to nucleic acid based methods for monitoring progression of breast or ovarian cancer in a subject, classified in class 435, subclass 6.

(Upon election of Group III, applicant must further choose one SEQ ID NO: SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 4, as contemplated in the specification as each nucleic acid molecule represents an independent species)

- IV. Claims 1-3, 6-8, and 14 in part as they apply to protein based methods, and claims 15-17 in their entirety drawn to protein based methods for diagnosing breast cancer in a subject, classified in class 435, subclass 7.1.

(Upon election of Group IV, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 15: as each polypeptide represents an independent invention, not a species.)

- V. Claims 18-20 and 22-24, in part as they apply to protein based methods, and claims 21 and 31-33 in their entirety drawn to protein based methods for assessing prognosis of a breast or ovarian cancer subject, classified in class 435, subclass 7.1.

(Upon election of Group V, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 31: as each polypeptide represents an independent invention, not a species.)

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- VI. Claims 34-36 and 38-40 in part as they apply to protein based methods, and claim 37 in its entirety drawn to protein based methods for monitoring progression of breast or ovarian cancer in a subject, classified in class 435, subclass 7.1.

(Upon election of Group VI, applicant must further choose one SEQ ID NO: SEQ ID NO: 2, SEQ ID NO: 5, or SEQ ID NO: 6, as contemplated in the specification as each polypeptide molecule represents an independent species)

- VII. Claims 41-43, drawn to methods for assessing a test compound, classified in class 436, subclass 501.

- VIII. Claims 45, drawn to kits for diagnosing a disease or assessing the suitability of a test compound based on nucleic acid analysis, classified in class 435, subclass 6.

(Upon election of Group VIII, applicant must further choose ONE nucleic acid molecule SEQ ID NO: from Claim 45, as each nucleic acid molecule represents an independent invention, not a species)

- IX. Claims 46 drawn to kits for diagnosing a disease or assessing the suitability of a test compound based on protein analysis, classified in class 435, subclass 4.

(Upon election of Group IX, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 46: as each polypeptide represents an independent invention, not a species.)

- X. Claims 47 and 50, drawn to, in part as it applies to an agent that binds a protein gene product, and claims 51 and 52 in their entirety, drawn to therapeutic agents that bind to protein gene products, classified in class 514, subclass 2.

(Upon election of Group X, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 51: as each polypeptide represents an independent invention, not a species.)

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XI. Claims 47 and 50 in part as it applies to an agent that binds nucleic acid and claims 53-55 in their entirety, drawn to therapeutics that bind to nucleic acids, classifiable in class 514, subclass 44.

(Upon election of Group XI, applicant must further choose ONE nucleic acid molecule SEQ ID NO: from Claim 53, as each nucleic acid molecule represents an independent invention, not a species)

Claims 48 and 49 are withdrawn because it is not possible to determine for which Group it is intended, upon amendment it will be rejoined to the appropriate Group for examination.

2. Claims 44 link(s) inventions VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and IV, II and V, and III and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).
4. In the instant case, the methods are related in that they involve examining the expression pattern of CXCL9 or FLJ20174 nucleic acid or protein gene product. The methods of inventions I-VI are materially distinct methods which differ at least in objectives, method steps, and criteria for success. The methods of inventions I and IV are distinct from the invention of II, III, V, and VI because inventions I and IV have the distinct objective of diagnosing breast cancer in a subject which involves the detection of a tumor and determining the type of cancer. The methods of inventions II and V are distinct from the inventions of I, III, IV, and VI because inventions II and V have the distinct objective of determining the prognosis of breast or ovarian cancer by comparing the expression pattern of CXCL9 or FLJ20174 in samples from one or more subjects suffering from a known type of breast or ovarian cancer and determining the prognosis based on the comparison. The methods of inventions III and VI are distinct from the invention of I, II, IV, and V because inventions III and VI have the distinct objective of monitoring the progression of breast or ovarian cancer in a subject having the distinct step of repeating the measurement of the expression pattern of CXCL9 or FLJ20174. The methods of inventions I-III and IV-VI are distinct each from the other because inventions I-III use nucleic acid based methods and methods IV-VI use protein based methods.

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5. Invention I-VI are not related to invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions I-VI neither recite nor require the method steps of invention VII and inventions I-VI has a different mode of operation and a different function than the methods for assaying test compounds of invention VII.

6. Inventions VIII and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of invention VIII can be used for a process other than disease diagnosis, for instance a probe that binds to SEQ ID NO: 1 could be used as a capture probe to affinity purify native nucleic acids, or to amplify a nucleic acid for an expression vector.

7. Inventions I-III are unrelated to inventions IX, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of invention I-III neither recites nor requires the kit of invention IX (kits for protein based diagnosis), or the therapeutic agents of inventions IX, X and XI

8. Inventions IX and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the kit of invention IX can be used for a process other than disease diagnosis, for instance a reagent that binds to a protein could be used to purify protein from cells, or to detect recombinant protein produced from an expression vector.

9. Inventions IV-VI are not related to inventions VII, VIII, X, and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein based method of invention IV-VI does not require the compound testing steps of invention VII, and invention IV-VI has a different function than the methods for assaying test compounds of invention VII; additionally, the methods of invention IV-VI neither recite nor require the products of the kit of invention VII, or the therapeutic products of inventions X or XI.

10. Invention VII is related as product and process of use with inventions VIII and IX. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kits of inventions VIII and IX can be used in different processes, as evidenced at least by their uses in inventions I-III and IV-VI.

11. Invention VII is unrelated to inventions X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method for assessing test compounds (invention III) neither recites nor requires the specific therapeutic agents of inventions X and XI.

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12. Inventions VIII, IX, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used in distinct methods, have different modes of operation (inventions VIII and XI are nucleic acid based; invention IX and X are protein based), and different functions (inventions IV and IX are kits for diagnosing; inventions X and XI are therapeutic agents).

13. Furthermore, searching all of the inventions I-IX would invoke a burdensome search. Some of the inventions have been classified separately. Thus, each of these inventions has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Although some of the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

14. Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

15. Species Elections for Groups I and II

A. Claims 1 and 18 are generic to the following disclosed patentably distinct species of genetic marker:

1) CXCL9

2) FLJ20174

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B. Claims 1 and 18 are generic to the following disclosed patentably distinct species of cancer:

- 1) breast
- 2) ovarian

C. Claims 1 and 18 are generic to the following disclosed patentably distinct species of the form nucleic acid:

- 1) mRNA
- 2) hnRNA
- 3) cDNA

D. Claims 1 and 18 are generic to the following disclosed patentably distinct species of the form nucleic acid detection:

- 1) specific binding under stringent hybridization conditions
- 2) amplifying the nucleic acid

16. Species Elections for Group III

A. Claim 34 is generic to the following disclosed patentably distinct species of genetic marker:

- 1) CXCL9
- 2) FLJ20174

B. Claim 34 is generic to the following disclosed patentably distinct species of cancer:

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- 1) breast
- 2) ovarian

C. Claim 34 is generic to the following disclosed patentably distinct species of assessing the expression pattern of a nucleic acid:

- 1) determining the level of expression
- 2) comparing expression patterns of CXCL9 or FLJ20174 in different tissue samples from the same subject

17. Species Elections for Group IV and V

A. Claims 1 and 18 are generic to the following disclosed patentably distinct species of genetic marker:

- 1) CXCL9
- 2) FLJ20174

B. Claims 1 and 18 are generic to the following disclosed patentably distinct species of cancer:

- 1) breast
- 2) ovarian

18. Species Elections for Group VI

A. Claim 34 is generic to the following disclosed patentably distinct species of genetic marker:

- 1) CXCL9
- 2) FLJ20174

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B. Claim 34 is generic to the following disclosed patentably distinct species of cancer:

- 1) breast
- 2) ovarian

C. Claim 34 is generic to the following disclosed patentably distinct species of assessing the expression pattern of a protein:

- 1) determining the level of expression
- 2) comparing expression patterns of CXCL9 or FLJ20174 in different tissue samples from the same subject
- 3) comparing the level of post-translational modification of CXCL9 or FLJ20174

19. Species Elections for Group VIII and IX

A. Claim 44 is generic to the following disclosed patentably distinct species of genetic marker:

- 1) CXCL9
- 2) FLJ20174

B. Claim 44 is generic to the following disclosed patentably distinct species of cancer:

- 1) breast
- 2) ovarian

20. Species Elections for Group X and XI

A. Claim 47 is generic to the following disclosed patentably distinct species of genetic marker:

- 1) CXCL9

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2) FLJ20174

B. Claim 47 is generic to the following disclosed patentably distinct species of cancer:

1) breast

2) ovarian

21. Species Elections for Group XI

A. Claim 50 is generic to the following disclosed patentably distinct species of agent:

1) antisense nucleic acid

2) RNA interference oligonucleotide

22. The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each species group A and B from each elected Group, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

24. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

26 Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

27. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

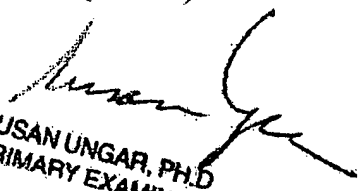
28. Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
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SUSAN UNGAR, PH.D.
PRIMARY EXAMINER